

**REMARKS UNDER 37 CFR § 1.116**

**Formal Matters**

Claims 1-13 and 17-20 are currently pending.

Claims 1-13 and 17-20 were examined. Claims 1-13 and 17-20 were rejected.

Applicant respectfully requests reconsideration of the application in view of the remarks made herein.

No new matter has been added.

**The Telephone Interview**

Applicant wishes to extend his appreciation to the Examiner for the courtesy provided to Applicant's representative during the telephone interview of February 23, 2007. During the Interview, the Examiner indicated that the rejection based on Crosby et al., U.S. Patent Publication No. 2003/0190689 would likely be withdrawn in view of Applicant's representative's remarks and that the Singh et al. reference would need to be considered in more detail after reading Applicant's remarks in writing in the response provided herein.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicant respectfully requests that the Examiner point out any deficiencies in his next communication so that Applicant can amend or supplement the interview summary.

**The Office Action**

**Claims Rejected Under 35 U.S.C. Section 102(b) (Singh et al.)**

Claims 1-13 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Singh et al. ("Gene expression correlates of clinical prostate cancer behavior", Cancer Cell, Vol. 1, March 2002). In the Examiner's "Response to arguments" section on page 3 of the Office Action, the Examiner asserted

that Singh et al. teaches on p. 209 (sic, 208), col. 1, 2<sup>nd</sup> full paragraph, that "...samples of prostate tumors adjacent prostate tissue not containing tumors (referred to as 'normal') were collected from patients...". The Examiner interpreted this statement to clearly and directly read on the claimed limitation of the heterogeneous tissue region. The Examiner further asserted that it is also clear that [a] plurality of samples were taken from a heterogeneous tissue region, in this case the plurality of samples is two samples.

Applicant respectfully submits that Singh et al. fails to disclose or inherently possess all features recited in independent claim 1. As Applicant noted in the previous response, Applicant respectfully submits that Singh et al. fails to disclose forming a plurality of characteristic signatures from measurements taken from samples taken from successive locations along a determined profile of locations through the heterogeneous tissue. The characteristic signatures formed by the present invention are location dependent, depending upon the profile of the locations through the heterogeneous tissue region. Thus, by comparing characteristic signatures with a trend profile of a measure property of the second type of tissue along the profile of locations, varying degrees of similarity of the characteristic signatures to the trend profile can be established. Singh et al. lacks any disclosure or suggestion of using such a technique.

Although Sing et al. discloses deriving expression profiles on page 204 under "tumor versus normal classification", these are not anticipatory of the currently recited characteristic signatures. Rather, an expression profile is a profile of various gene expression levels taken at a single sample location, by processing on a microarray having probes for different genes, as is a typical procedure commonly practiced in the art. Genes are then ranked by differential expression of tumor to normal levels. Characteristic signatures are not used, and thus there is not a signature that is formed from tumor and normal gene expression values read from a determined profile of locations. Further, there is no trend profile to which any characteristic signature could be compared. Rather, the genes are simply ranked by preparing differential expression levels of various genes and then ranking these differential expression levels. Further, the normal tissue values and tumor tissue values are compared across multiple tissue regions from multiple patients, whereas the presently claimed invention takes samples from successive locations of the same heterogeneous tissue region.

For at least the above reasons, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-13 under 35 U.S.C. Section 102(b) as being anticipated by Singh et al. ("Gene expression correlates of clinical prostate cancer behavior", Cancer Cell, Vol. 1, March 2002), as being clearly inappropriate.

**Claims Rejected Under 35 U.S.C. Section 102(e) (Crosby et al.)**

Claims 1-10, 12-13 and 17-20 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Crosby et al. (US Patent Application Publication No. 2003/0190689). In the Examiner's "Response to arguments" section on page 3 of the Office Action, the Examiner asserted that Crosby et al. discloses multiple embodiment in which characteristic signatures are formed from values of a particular property. Specifically, the Examiner referred to paragraph [0024] as identifying four novel biomarkers for predicting breast cancer responsiveness and four novel biomarker for predicting glioma cancer, thereby forming a plurality of characteristic signatures. The Examiner further asserted that paragraph [0025] discloses the correlation of the biomarkers detected among all patients and the disease state.

Applicant respectfully submits that Crosby et al. fails to disclose or inherently possess all features recited in independent claims 1, 17 and 18. As noted by the Examiner, Crosby et al. obtains cellular samples from a plurality of patients (see paragraph [0025]). The biomarkers are then used to evaluate these samples. Crosby et al. does not disclose a plurality of samples being taken from successive locations along a determined profile of locations through a heterogeneous tissue region. It therefore follows that Crosby et al. cannot form characteristic signatures based on such samples, or a trend profile.

For at least the above reasons, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-10, 12-13 and 17-20 under 35 U.S.C. Section 102(e) as being anticipated by Crosby et al. (US Patent Application Publication No. 2003/0190689), as being clearly inappropriate.


**Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10030215-1.

Respectfully submitted,

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